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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,642

06/20/2006

Timothy John Norman

CELL-0317

3724

20306

7590

04/15/2008

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/583,642	<b>Applicant(s)</b> NORMAN, TIMOTHY JOHN	
	<b>Examiner</b> PAUL DICKINSON	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |



### **DETAILED ACTION**

Applicant's election without traverse of DiFab'-conjugated 3-maleimidyl-N-(2-[[3-maleimidyl-propionyl]-[(2-(methoxy-polyethoxy)-ethylcarbamoyl)-methyl]-amino}-ethyl)-N-[(2-(methoxy-polyethoxy)-ethylcarbamoyl)-methyl]-propionamide in the reply filed on 2/7/2008 is acknowledged.

No prior art against the elected species was found. The search was therefore expanded to nonelected embodiments, which is set forth in the prior art rejection below. The search was not extended to the entire scope of the claims since prior art was found for the generic claim. Claims 1 and 8 are currently under consideration. Claims 2-7 are withdrawn as not reading on applicant's elected species or that cited below by the examiner to reject the claims.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims fail to meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural



information for “polymer residue”. Chemical species encompassed by this phrase are vast in number and their chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of polymer residue as recited by the claims, since there is no description of the structural relationship of these residues provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a residue.

The appearance of mere indistinct words (here the word “inhibitor”) in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing “sufficiently detailed, relevant identifying characteristics,” including “functional characteristics when coupled with a known or disclosed correlation between function and structure.” Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here; at best all that can be inferred from the instant specification is that compounds having the general formulae set forth at page 5 of the specification inhibit



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the production of downstream products of 14 kD PLA<sub>2</sub>, such as arachidonic acid. See the first paragraph on page 13. Whether this was specifically due to inhibition of enzyme activity, or also due inhibition of production, transcription or translation, or some combination of these, is not clear from the data presented.

The examiner recognizes that the fact situation in the Rochester cases was extreme, with Applicant disclosing there no (or possibly one) specific compounds. The reasoning provided by the court can be fairly extended to less extreme situations (*i.e.*, where a limited number of species is actually disclosed, such as here), however, given the court's recognition that:

[I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. Rochester (2003) at 1431.

As was the case in Rochester, there is no such specificity here, nor could one skilled in the art identify any particular compound, other than those having the general formula set forth at the top of page 5 of the specification, as being able to inhibit any particular mechanism of 14 kDa PLA<sub>2</sub> action, other than to inhibit its "activity" in some unspecified way.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

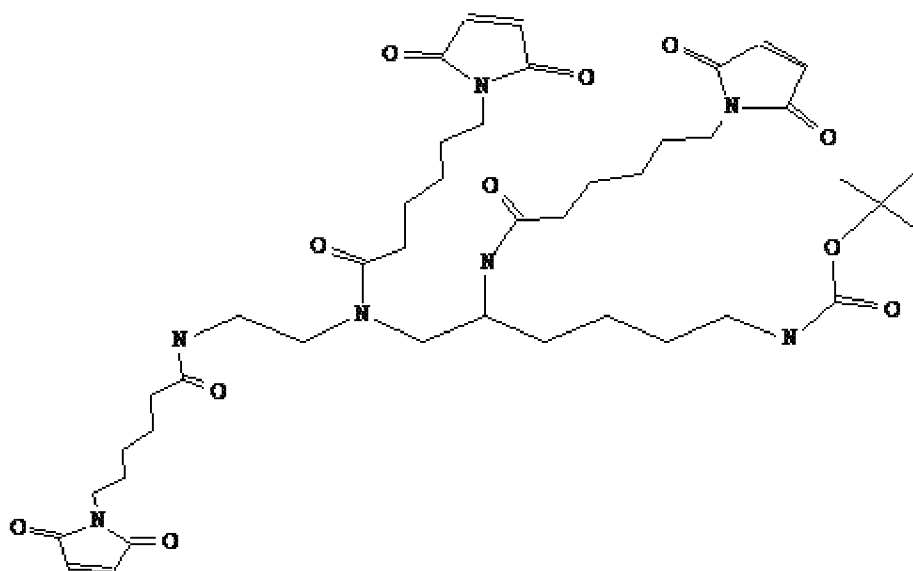
A person shall be entitled to a patent unless –



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Norman et al (Norman et al, Improved Tumour Targeting with Recombinant Antibody-Macrocyclic Conjugates, J. Chem. Soc., Chem. Commun., 1995, 1877-1878). Norman et al discloses the following compound:



(see page 1877, compound 7). This compound matches formula I of the instant claim as follows:

$P^1$ =1-pentyl-1*H*-pyrrole-2,5-dione

$A^1$ =CONH

$W^1$ =(CH<sub>2</sub>)<sub>2</sub>

$X^1$ =N

$V^1$ =covalent bond



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$B^1 = \text{CO}$   
 $Y^1 = (\text{CH}_2)_4$   
 $L^1 = (\text{CH}_2)_1$   
 $Z^1 = 1H\text{-pyrrole-2,5-dione}$

$M^1 = (\text{CH}_2)_1$

$P^2 = \text{OC}(\text{CH}_3)_3$   
 $A^2 = \text{CONH}$   
 $W^2 = (\text{CH}_2)_4$   
 $X^2 = \text{CH}$   
 $V^2 = \text{covalent bond}$   
 $B^2 = \text{NHCO}$   
 $Y^2 = (\text{CH}_2)_4$   
 $L^2 = (\text{CH}_2)$   
 $Z^2 = 1H\text{-pyrrole-2,5-dione}$

$n=0$

The Examiner is interpreting the term “polymer residue” to encompass  $P^1$  and  $P^2$  above.

### ***Allowable Subject Matter***

Claim 8 has been examined only to the extent that it reads on the elected species. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

No claim is allowed.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

April 8, 2008